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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,510	10/19/2001	Ben-Zion Dolitzky	1662/54902	5381

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EXAMINER	
BARTS, SAMUEL A	
ART UNIT	**PAPER NUMBER**
1621	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,510	DOLITZKY ET AL.	
	Examiner	Art Unit	
	Samuel A Barts	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) *93 and 94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 95-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/30/2004 have been fully considered but they are not persuasive.

Applicants have argued that their invention does not rest on purity alone, but that they were the first to achieve a venlafaxine base as a white crystalline solid. They also argue that they have discovered a novel crystallization method for making said white crystalline solid. The argument with respect to the crystallization method is irrelevant because the elected invention is not directed to a process of making said crystals. The argument that applicant's invention is the discovery of white crystals of venlafaxine is not convincing. The whiteness of the crystal is an inherent property of the crystal. Applicant has done nothing to make the crystals white other than purifying venlafaxine base.

As stated by applicant the venlafaxine base was considered yellow in the WO '555 publication. The examiner has already admitted that the white crystals and/or a more purified venlafaxine base were not disclosed in the prior art. The real question is whether or not it was obvious to purify the venlafaxine base disclosed in WO '555.

As stated in the first office action, it has been well established that the mere purity of compound, in itself, does not render a substance unobvious Ex parte Gray (BPAI 1989) 10 PQ2D 1922. The color of the crystal has no

patentable weight because the color is simply an inherent property of the final pure crystals. One skilled in the art would be motivated to make a very pure composition of venlafaxine to eliminate the possibility of side effects that might be associated with the impurities.

Applicant's argument that a skilled artisan would be dissuaded from even attempting to isolate venlafaxine base because they would expect to obtain a difficult to handle oil or gum has been considered. The examiner does not agree. Venlafaxine base is a well-known compound useful for treating depression. One of ordinary skilled in the pharmaceutical art would fundamentally be motivated to purify an active compound in order to determine the source of the different side effects that might be associated with the compound. The side effects that are observed in clinical studies often times are attributable to impurities or even to one of the enantiomers. Therefore, skilled artisans routinely purify these pharmaceutically active compounds in order to have a better understanding of the desired and undesired effects associated with the compounds. The qualitative analysis override the possible difficulty associated with purifying the compound. Therefore, the examiner does not find applicant's argument convincing and is maintaining the rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2 and 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jerussi et al (WO 00/32555). For reasons see previous office action.

Claims 95-98 are directed same crystals made by a process. M.P.E.P. 2113 states the following

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The examiner's rationale for why claims 1-2 are obvious also renders obvious claims 95-98. These claims are simply directed to a purer form of a well-known pharmaceutical compound. Purifying this well-known pharmaceutical is obvious for reasons already stated.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel A Barts
Primary Examiner
Art Unit 1621

SB